

REMARKS:

In the Office Action dated July 16, 2007, claims 14, 15, 18-20 and 25-29 were rejected under 35 U.S.C. §102(b) as being anticipated by Gilli. Claims 16, 17 and 21-24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gilli in view Grevis et al.

These rejections are respectfully traversed for the following reasons.

Applicants acknowledge that the Gilli reference discloses a procedure for operating an implantable device that is capable of operating in a bradycardia pacing mode and is also operable, when necessary, in an antitachyarrhythmia pacing mode as well as in a defibrillation pacing mode. As shown in Figure 4 of the Gilli reference, in decision block 90, after tachyarrhythmia has been successfully reverted, a time-out occurs after which the procedure reverts to the bradycardia pacing mode. The same situation occurs in decision block 93 following a time-out after successful reversion of fibrillation.

In both instances, however, the procedure reverts to block 81, wherein the pacing energy is set to normal settings. Therefore, the "normal" operation of the bradycardia pacing mode in the Gilli reference is to employ predetermined settings, and this same "normal" mode with pre-settings is reverted to after the successful termination of tachyarrhythmia or fibrillation.

In claim 14 as originally filed, by contrast, the pacing pulse generator is operable by the control unit in either of two modes, namely a first mode that includes an autocapture mode, and a second mode with predetermined settings for the pacing pulses. There is no mention of a mode of operation in the Gilli reference that corresponds to the first mode in independent claim 14, wherein an autocapture routine is executed. As noted above, in the Gilli reference, bradycardia pacing always takes place according to predetermined settings. As explained in the paragraph bridging pages 2 and 3 of the substitute specification, and in the following paragraph beginning at line 3 of page 3 of the substitute specification, the present Applicants have recognized that autocapture measurements, if made immediately following the delivery of a high-energy shock, may result in a higher pacing threshold being

determined as a result of the autocapture routine than is actually necessary. For many reasons, however, it is normally desirable to operate in a pacing mode that includes an autocapture mode that is executed as often as necessary to ensure that a higher-than-necessary pacing pulse amplitude is not being employed. The present Applicants have had the insight to recognize that this desirable, normal operation in a pacing mode that includes execution of an autocapture routine can be retained, even in the context of an implantable device that also delivers high-energy shocks, by switching to a second pacing mode wherein, instead of using an autocapture routine to set the pacing pulse amplitude/energy, predetermined settings are used. After the temporary trauma to the myocardium following delivery of a high-energy shock has subsided, operation then can revert back to the normal mode wherein pacing pulse amplitude/energy is determined according to the autocapture routine.

As noted above, the Gilli reference does not provide any disclosure regarding the use of an autocapture routine, and therefore the disadvantages of bradycardia pacing based on levels set with an autocapture routine do not exist in the Gilli stimulator, and therefore there is no need to switch between a first pacing mode wherein the autocapture routine is used, and a second pacing routine wherein predetermined settings are used. The only description in the Gilli reference regarding operation in the bradycardia pacing mode occurs at column 4, lines 45-54, and this makes no mention of executing an autocapture routine. The description of the block 81 in Figure 4 at column 5, lines 50-56 of the Gilli reference explicitly states that in block 81, the pacing energy is set to the normal value corresponding to 4 volts.

Even though claim 14, as noted above, set forth the aforementioned first and second pacing modes in the claim language that was originally presented, claim 14 has been editorially amended to make clear that the control unit normally operates the pacing pulse generator in the first pacing mode, i.e., the mode wherein an autocapture routine is executed. Support for this added language is present in the original PCT application at page 11, lines 7-14, and in the substitute specification at page 10, lines 22-27. The

language describing the switchover to the second mode of operation of the pacing pulse generator, following delivery of a shock by the high energy pulse generator, also has been editorially revised.

5 Since the Gilli reference does not disclose operation in a bradycardia pacing mode employing an autocapture routine, and therefore provides no indication of any disadvantages of executing such an autocapture routine following delivery of a high-energy shock, the Gilli reference does not disclose or suggest all of the elements of claim 14, and thus does not anticipate claim 14, nor any of claims 15, 18-20 or 25-29 depending therefrom.

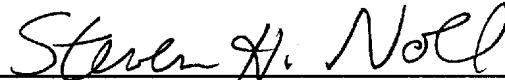
10 Moreover, dependent claims 15 and 18 describe conditions that must be satisfied in order for the control unit, after operating in the second pacing mode, to switch operation of the pacing pulse generator back to the first pacing mode. Since there is no bradycardia pacing disclosed in the Gilli reference that would correspond to the first mode of operation set forth in
15 claim 14, the Gilli reference does not, and cannot, provide any disclosure or suggestion regarding conditions for leaving the second pacing mode and reverting back to the first pacing mode.

The above arguments are also applicable to the rejection of claims 16, 17 and 21-24 under 35 U.S.C. §103(a) as being unpatentable over Gilli and
20 Grevis et al. The Examiner relied on the Grevis et al. reference as disclosing certain time intervals, but, as noted above, such time intervals, even if described in the Grevis et al. reference, have no applicability to switching between first and second pacing modes, because such switching between first and second pacing modes is not disclosed at all in the Gilli reference.
25 Claims 16, 17 and 21-24, therefore, would not have been obvious to a person of ordinary skill in the field of designing implantable cardiac stimulators.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is therefore respectfully requested.

Submitted by,

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(Reg. 28,982)

SCHIFF, HARDIN LLP

CUSTOMER NO. 26574

Patent Department

6600 Sears Tower

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233 South Wacker Drive

Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants.